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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/508,873	12/06/2004	Hilmar Meek Warenus	185737/US	1109

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EXAMINER

HALVORSON, MARK

ART UNIT PAPER NUMBER

1642

DATE MAILED: 10/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/508,873	WARENIUS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Mark Halvorson	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 18-28 is/are pending in the application.
- 4a) Of the above claim(s) 6, 9-15 and 18-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7 and 8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Claims 1-15, 18-28 are pending.

### ***Election/Restrictions***

2. Applicant's election without traverse of Group 1 in the reply filed on June 29, 2006 is acknowledged. Applicant's species election of (1) master regulatory gene product which regulates the levels of other gene products involved in cell cycle and apoptosis pathways, (2) agent capable of altering the ratio of the CDK1 and CDK4 gene product in a cancer cell and (3) CDK4 as the critical normal gene product is acknowledged. Claim 9-15, 18-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claim 6 is a withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Claims 1-5, 7 and 8 are under prosecution.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Kelly et al WO 98/49146, (publication date 5 November 1998).

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Claims 1, 2, 7, and 8 are drawn to a method of screening for an agent effective in the treatment of a cancer, which method comprises selecting a putative agent that is likely to disrupt a function mediated by CDK4 and treating a cancer cell sample and a control cell sample with the putative agent, and determining growth inhibiting effect of the putative agent on these samples and identifying an effective agent as an agent which is more inhibiting to the growth of the cancer cell sample than the control cell sample.

Kelly et al discloses a method for detecting inhibitors of CDK4 and identifies compounds that are more active against cancer cells than normal controls. (page 21 lines 8-26).

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 3–5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelly et al as applied to claims 1 and 2, above, and further in view of Theryte Limited (WO 99/42821, publication date 26 August 1999).

Claims 3-5 are drawn to a method of screening for an agent effective in the treatment of a cancer, which method comprises selecting a putative agent that is likely to disrupt a function mediated by CDK6 and treating a cancer cell sample and a control cell sample with the putative agent, and determining growth inhibiting effect of the putative agent on these samples and identifying an effective agent as an agent which is more inhibiting to the growth of the cancer cell sample than the control cell sample, wherein the cancer cell sample consists of cancer cells in which the ratio of the levels of the CDK1 and CDK4 gene products is in the range of 0.6 to 1.6, wherein the cancer cell sample consists of cells in which the CDK1 and CDK4 gene products are both elevated as compared with control cells, and wherein the step of identifying an effective agent further involves determination of the ratio of the levels of the CDK1 and CDK4 gene products in the cancer cell sample before and after treatment with the putative agent.

Kelly et al has been described supra.

Kelly et al does not disclose a cancer cell sample that consists of cells in which the CDK1 and CDK4 gene products are both elevated as compared with control cells in which the ratio of the levels of the CDK1 and CDK4 gene products is in the range of 0.6 to 1.6.

Theryte discloses that CDK1 and CDK4 proteins are elevated in cancer cells (Figs. 3 and 4) and that the ration of CDK4 to CDK1 is approximately 1 (Fig 5).

One of ordinary skill in the art would have been motivated to apply Theryte's teaching of the diagnostic value of CDK1 and CDK4 levels in cancer to Kelly et al drug screen method because Theryte states that the increased levels of CDK1 and CDK4 in cancers may be used in drug screening that might lead to more specifically toxic to cancer tissues (page 3, 3<sup>rd</sup> paragraph). Thus, it would have been prima facie obvious to combine Kelly et al's method for detecting CDK4 inhibitors with Theryte's finding of elevated levels of CDK4 and CDK1 in cancer.

### ***Summary***

8. No claims allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halvorson, PhD whose telephone number is (571) 272-6539. The examiner can normally be reached on Monday through Friday from 8:30am to 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Halvorson, PhD  
Patent Examiner  
571-272-6539

A handwritten signature in black ink, appearing to read "Misook Yu", with a stylized flourish at the end.

**MISOOK YU  
PRIMARY EXAMINER**